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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WALLENHORST, MAUREEN

ART UNIT PAPER NUMBER

1743

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/974,044

Applicant(s)

COHEN ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al in view of Beck et al.

Nguyen et al teach of a web-based computer program in the form of a web-site on the internet for the diagnosis of coagulation disorders. The program is known as WEB COAG, and it includes an algorithm therein for comparing clinical hemostasis results with a database of

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known coagulation disorders. A coagulation profile is included in the program, which contains a decision tree of typical results from seven screening coagulation tests for each disorder. The tests include prothrombin time, activated partial thromboplastin time, fibrinogen, etc. A differential diagnosis component is present in the program that generates a list of disorders which a particular diagnostic test pattern entered by a user is compared to in order to make a diagnosis. In addition, the program includes a coagulopathy and therapy component that displays essential information on various coagulation disorders and current therapeutic options. Information on disorders includes biochemical aspects, treatment and diagnostic criteria. To use the program taught by Nguyen et al, a user enters hemostasis analysis results into the program on the web page. The inference algorithm compares the entered hemostasis results with the database of known test results from different coagulation disorders. The decision tree, as depicted in Figures 1 and 2 of Nguyen et al, is used to determine which of the patterns of coagulopathies matches the entered hemostasis results. The decision tree includes analysis criteria such as normal and abnormal prothrombin results, normal and abnormal fibrinogen results, etc. The web page taught by Nguyen et al is present on a computer with a memory and processor, and is wirelessly connected to other computers over the internet (i.e. a communication network).

Nguyen et al fail to teach of a hemostasis analyzer associated with the coagulopathy web page. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to realize that a hemostasis analyzer is associated with the decision tree and analysis criteria taught on the web page of Nguyen et al since a hemostasis analyzer must be used to measure the patient coagulation data entered into the program. Nguyen et al also fail to

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teach that the hemostasis analyzer used to measure the clinical coagulation properties of a sample that are entered into the web page can be coupled to the web page by a communication link.

Beck et al teach of a medical access device in which a medical device such as a coagulation monitor is connected to a communication network that allows remote access by users to the medical device. The device comprises a medical sensor 130 such as a sensor for measuring blood coagulation (see paragraph no. 2 on page 1 and paragraph no. 34 on page 4 of Beck et al), which is connected to a computing device 120 such as a computer through a wireless communications interface 136. The computer 120 is connected to a communications network 150 through a network interface 125. The network 150 is in turn connected to a server computing device 110 that receives measurement data from the medical sensor 130 through the network 150. The server computing device 110 serves to analyze the measurement data and provide the computing device 120 with results data. The server computing device 110 provides a user with an anonymous mechanism for analyzing their current measurement data. The network 150 utilizes the internet to provide access to the server computing device 110 from the computer 120 connected to the medical sensor 130. The server computing device 110 comprises a memory 114, a processor 112 and a network interface 118 for receiving the medical data from the sensor 130 to calculate medical parameters and properties of a patient. See Figure 1 in Beck et al.

Based upon the combination of Nguyen et al and Beck et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to couple the hemostasis analyzer used to measure the clinical coagulation properties of a sample in the apparatus taught by Nguyen et al directly to the web page by a communication link since Beck et al teach that it is known to couple blood coagulation sensors directly to a communication network in order to

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directly send hemostasis measurement results to a universal data calculation unit which calculates a hemostasis result that can be posted over the network for many users to view.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Roman et al, Avitall, Kwong and WO 01/50950 who teach of a patient data collection system connected to a communication network; and Cohen and Cohen et al (US Patent nos. 6,537,819 and 6,225,126) which teach of blood coagulation measurement devices.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 703-308-3912. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maureen M. Wallenhorst  
Primary Examiner  
Art Unit 1743

mmw

October 20, 2003

*Maureen M. Wallenhorst*  
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